

Remarks

Claim 107 has been added. Claims 1-10 and 60-107 are pending in the application. Claims 5-10, 66-71, 76-77, and 79-106 have been withdrawn from consideration as being drawn to a non-elected invention. Claims 1-4, 60-65, 72-75, 78, and 107 are currently under consideration.

The term "regulates" in claims 1, 60, 63-64, finds support in the specification at pages 3-4 and page 48, lines 7-10. The amendments to claims 60 and 72-75 to recite % identity find support in the specification at page 9, line 32 to page 10, line 5, page 23, lines 16-30, page 25, line 18 to page 26, line 7, and page 27, lines 10-17. The amendment to claim 72 reciting the length of the probe or primer finds support at page 36, lines 25-30. The amendments to claim 75 to recite hybridization conditions are exemplified on pages 26-27. Claim 107 has basis in the application on, for example, page 12, lines 18-37. All other amendments are generally formal in nature, and are supported by the specification as filed, and claims as originally recited.

The issues and rejections set forth in the August 21, 2003 Office Action have been reviewed and are summarized herein.

First, the Examiner notes that the restriction requirement has been made final.

Next, the Examiner points out several formal matters which require correction, including removing browser executable code, correcting an abbreviation, and amending claims so that they read only on the elected invention.

The Examiner has rejected claims 1-4, 60-65, 72-75, and 78 under 35 U.S.C. §112, second paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter that applicants regard as the invention.

The Examiner has rejected claims 1-2, 60-63, 65, 72-75,

and 78 under 35 U.S.C. §112, first paragraph, as allegedly lacking an adequate written description in the specification.

The Examiner has rejected claims 1-4, 60-65, 72-75, and 78 under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement.

The Examiner has rejected claims 1-4 and 60-65 under 35 U.S.C. §102(b), as allegedly anticipated by Schmidt et al., Science (1995) 270:480-483.

Finally, the Examiner notes that claims 72-75 and 78 are free of the prior art.

The foregoing constitutes the entirety of the objections and rejections set forth in the August 21, 2003 official action. Applicants respectfully submit that the claims as presently amended are in condition for allowance. Each of the above-noted rejections under 35 U.S.C. §§112, first and second paragraphs and 102 is, therefore, respectfully traversed.

Specification

The Examiner has objected to the disclosure because it contains an embedded hyperlink and/or other form of browser executable code. In accordance with the Examiner's requirements, applicants have deleted the objected material (<http://>). Inasmuch as the link is no longer active, Applicants submit that this objection has been rendered moot.

Claim Objections

The Examiner has objected to claims 3 and 4 for use of the abbreviation "No." The Examiner requires the abbreviation be amended to recite "NO". Applicants have amended the claims accordingly, and request withdrawal of this objection.

The Examiner has also objected to claims 60-61, 63-64, 72-75, and 78, for reading on non-elected subject matter. Applicants respectfully submit that the claims as amended are

drawn to the elected subject matter.

**The Claims as Amended Fully Meet the Requirements of 35 U.S.C.
§112, Second Paragraph**

The Examiner has rejected claims 1-4, 60-65, 72-75, and 78 under 35 U.S.C. §112, second paragraph, as allegedly vague and indefinite.

First, the Examiner indicates that the metes and bounds of "obtainable" in claim 1, and all subsequent claims cannot be determined. Applicants respectfully submit that the metes and bounds of "obtainable" are clear, and mean capable of being obtained, or available. However, solely in the interest of expediting prosecution, the claims have been amended to read "obtained". One skilled in the art would know whether or not a nucleic acid had been obtained from the VRN2 locus.

Next, the Examiner states that the recitation "VRN2 locus" in claim 1 has not been defined. However, contrary to the Examiner's assertion, the VRN2 locus has been defined by mapping, as described in the application on e.g. pages 48-49. The position of the VRN2 locus is therefore clear from the description.

The Examiner then sets forth that the metes and bounds of "capable" in claim 1, and all subsequent claims have not been defined. Then the Examiner indicates that the metes and bounds of "affecting" in claim 1 and all subsequent claims have also not been defined. It is submitted that these terms are clear. However, in the interests of swiftly advancing this application, the terms are deleted and replaced by "regulates".

The Examiner next states that the metes and bounds of "vernalization response" in claim 1 have not been defined. The Examiner is concerned that it could be unclear what

"responses" are included in the "vernalization" process. The phrase "vernalization response" is routinely used in the art of plant propagation and is clear to the skilled person.

Vernalization is essentially the promotion of flowering in plants by the application of cold treatment. Some plants require a period of cold (vernalization period) in order to flower. Other plants do not have this requirement, or have a lesser requirement for vernalization. The present inventors have shown that VRN2 is able to change the vernalization requirement of a plant prior to flowering. Thus, Example 1 (see pages 46-47) shows that the mutant fca-1 vrn2-1 plants required a longer period of vernalization in order to flower, i.e. the flowering time increased compared to plants having normal vrn2 expression. To the person skilled in the art, the vernalization response is a familiar concept. Accordingly, no lack of clarity is generated by the use of this phrase in the claims.

With regard to claim 60, the Examiner first indicates that the recitation "variant" has not been defined. Next, the Examiner indicates that the recitation "homologous" has not been defined. It is submitted that these terms are well known in the art. Further, both terms are clearly described in the specification, for example at page 9, line 20-page 11, line 22. However, in the interest of swiftly advancing this application, the terms have been deleted, except in claims 60 and 63, where the claims specifically describe what is encompassed by the term "variant", as required by the Examiner.

The Examiner then states that in line 5 of claim 60, the word "sequence" needs to be inserted after "identity". The Examiner also requires that the word "homology" be replaced with --sequence identity-- in claim 63. Applicants respectfully submit that the claims as originally presented

are clear. Nonetheless, Applicants have amended claim 60 in accordance with the Examiner's helpful suggestion, and have deleted the language found objectionable in claim 63.

In claim 64, the Examiner indicates that the phrase "which is a fragment of a sequence..." is unclear. Applicants respectfully submit that the phrase as originally recited is clear. Nonetheless, claim 64 has been amended to make clear that the claimed nucleic acid comprises a sequence that is a fragment of SEQ ID NO: 1.

In claim 72, the metes and bounds of "partly" and "substantially" have allegedly not been defined. Applicants respectfully submit that these terms as originally presented are well known in the art, and are therefore, clear. To further clarify, claim 72 has been amended to recite that the sequence is at least 90 % identical between the sequences mentioned. Also, the length of the probe or primer is now at least 15 nucleotides. Accordingly, the terms "partly" and "substantially" have been deleted.

The Examiner also requires that the word "to" be inserted before the word "claim" in claim 74, line 2. Applicants have amended the claim in accordance with the Examiner's helpful suggestion.

Finally, in claim 75, the Examiner indicates that the "conditions of hybridization" have not been defined. Accordingly, claim 75 as amended specifies that the conditions are those of high stringency. It would be inappropriate in a method claim to recite the exact conditions for hybridization, owing to the range of conditions that are available to the skilled person. In other words, there are many means to the same end. Page 26, line 36 to page 27, line 26 of the application details various conditions for hybridization, including high stringency conditions for detecting very similar sequences. The claim is directed to a method of

detecting SEQ ID NO: 1 using a conserved probe sequence and, given this purpose, the skilled person knows to use appropriately stringent conditions, particularly in light of the extensive teachings in the specification. Accordingly, there is no lack of clarity in claim 75.

In conclusion, in light of the foregoing remarks and amendments to the claims, applicants respectfully request withdrawal of the rejections under 35 U.S.C. §112, second paragraph.

The Claims As Amended Fully Meet the Written Description Requirement of 35 U.S.C. §112, First Paragraph

The Examiner has rejected claims 1-2, 60-63, 65, 72-75, and 78 under 35 U.S.C. §112, first paragraph, as allegedly lacking written description. Applicants respectfully traverse this rejection. As noted in the MPEP at § 2163,

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.

Furthermore, the written description guidelines set forth in the Federal Register Vol. 66, No. 4, January 5, 2001 state that "An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics, so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention." (page 1105, column 3). "An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that the applicant was in possession of the claimed invention, ie: complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed

correlation between function and structure, or some combination of characteristics." (Page 1106, column 1).

Applicants respectfully submit that the instant specification contains sufficiently detailed, relevant identifying characteristics which provide evidence that the applicants were in possession of the claimed invention. Specifically, the specification discloses the sequence of VRN2 cDNA from *Landsberg erecta*, as well as the sequences of VRN2 from *Columbia*, and allelic/alternatively spliced forms of the same. Further applicants have linked these specific structures to a specific function. For example, the VRN2 sequences of the invention are shown to affect physical characteristics of a plant, including vernalization response, flowering time, leaf size, shape, and shade avoidance response. Thus, the claimed invention provides a specific structure, which is linked to a specific function.

Regarding the Examiner's assertion that the applicants do not specify start or stop codons of SEQ ID NO: 1, nor disclose structural, physical or chemical properties for the sequence, applicants submit that these assertions are unjustified. The application does indicate start and stop codons in SEQ ID NO: 1, and characterization of the sequence is included in the description. Figure 6 shows SEQ ID NO: 1, the sequence of VRN2 cDNA from *Landsberg erecta*. The start and stop codons are clear from the alignment with the translation, i.e. the coding sequence begins at nucleotide 231 and ends at nucleotide 1565.

The Examiner also asserts that the application fails to describe structural, physical, and/or chemical properties of the claimed sequence. Again, contrary to this assertion, disclosure of structural/physical/chemical properties of VRN2, is provided throughout the specification. See for example the section entitled "Analysis of the VRN2 gene" beginning on page

53 of the application. A number of domains are identified in the sequence, and some of this information is shown in Table 2 (page 66) and in Figure 6.

Claim 60 as amended recites 90 % sequence identity, thus restricting the claims to sequences having a very close relationship to SEQ ID NO 1.

The Examiner also objects that the written description requirement is not satisfied because one of skill in the art would not be able to identify sequences with less than 100 % identity that still maintained the claimed activity. However, in fact, methods of identifying variants are routine in the art and pose no difficulty to the skilled person. The skilled person can straightforwardly identify variants using well-known methods, examples of which are given in the specification. For example, page 6 describes how homologues may be obtained from cDNA libraries using hybridization probes. This and other methods are described in more detail on pages 23-29, for example.

Because of the functional features in the claims, the claims do not cover sequences that lack the "proper activity", and activity can and would be routinely determined by the skilled person whenever a potential variant is identified.

Some variants are explicitly exemplified in the application. In addition to SEQ ID NOS 1 and 2 from *Landsberg erecta*, the application shows the sequences of VRN2 from *Columbia* (SEQ ID NOS: 3, 4 and 6) and allelic/alternatively spliced forms of these (SEQ ID NOS: 7 and 8), as noted on page 5 lines 5-34.

Thus, not only are some variants already disclosed in the application, but the skilled person can readily use these sequences to obtain further variants using standard techniques set out in the description.

New claim 107 relates to nucleic acid that hybridizes to

the complement of SEQ ID NO: 1 under high stringency conditions which are described in the specification at pages 26-27. The language of this claim is closely based on Example 9 of the "Synopsis of Application of Written Description Guidelines" (see annex), where the example claim is said to meet the written description requirement. Thus, it is Applicants' position that this claim fully satisfies the requirements of 35 U.S.C. §112, first paragraph.

In summary, because the application does contain relevant identifying characteristics of sequences isolated from the VRN2 locus thereby providing evidence that the applicants were in possession of the claimed invention, including complete structure, other physical and/or chemical properties, and functional characteristics coupled with a disclosed correlation between function and structure, applicants respectfully submit that the subject matter encompassed by the claims was fully described in the application as filed. Accordingly, withdrawal of the rejection under 35 U.S.C. §112, first paragraph is warranted and such action is earnestly solicited.

**The Claims As Amended Fully Meet the Enablement Requirement of
35 U.S.C. §112 First Paragraph**

The Examiner has rejected claims 1-4, 60-65, 72-75, and 78 under 35 U.S.C. §112 first paragraph, as allegedly lacking enablement.

The Examiner sets forth numerous reasons for the assertion that the claims lack enablement. The Examiner indicates that applicants have not taught how one skilled in the art can make and/or use the claimed sequences to affect the specified physical characteristics of a plant into which the nucleic acid is introduced. The Examiner also states that the applicants have not taught a method of selecting a plant

having a desired allele of the VRN2 gene using the specified probe or primer. Further, the Examiner indicates that applicants have not taught a method for determining the presence of the claimed nucleic acid by hybridization using the specified probe or primer.

The nucleic acids and methods of the invention are enabled, because it is straightforward for the skilled person to use the explicitly provided sequences to identify and obtain related sequences falling within the scope of the claims. Description of appropriate techniques for identifying and/or obtaining such nucleic acids occupies a large part of the application. For example, see pages 23-37.

The required techniques are familiar to one skilled in the art and do not give rise to an undue burden of experimentation, particularly for obtaining very closely related sequences such as those claimed in claim 60 or in the methods of claims 72-75 and 78.

Regarding the Examiner's point about the identity of the "VRN2 locus" (page 10 of the office action) as addressed above, the VRN2 locus has been defined by mapping, as described in the application on e.g. pages 48-49. Further, regarding the Examiner's point that an apparently related sequence appears quite close to VRN2 on chromosome 4 of *A. thaliana*, this other sequence should not cause confusion over the term "VRN2 locus". Although it does share some sequence similarity, it remains clear that it is not the VRN2 gene. Genes can occur in clusters of related sequences, thought to represent ancestral gene duplication in the evolutionary past. However, the skilled person recognizes that the different genes are distinct and, based on the disclosure in the application, knows how to locate the VRN2 locus.

The Examiner objects that one skilled in the art cannot obtain variants of SEQ ID NO: 1 that have the claimed

function, with reference to Bowie et al. However Bowie et al., teach that "proteins are surprisingly tolerant of amino acid substitutions" (page 1306, right column). Accordingly, the skilled person can readily obtain variants by, for example, mutagenesis of SEQ ID NO: 1, or by probing a genetic library. The skilled person can ensure production of a functional variant by testing the mutant sequences for function. If, by chance, the mutated sequence no longer functions as recited in the claim, then the nucleic acid is outside the scope of the claim.

In *In re Wands*, 8 USPQ2d 1400 (1988), the Federal Circuit Court of Appeals held that engagement in experimentation to practice a claimed invention does not render the disclosure non-enabling as long as the experimentation required is not "undue". The Court stated that: "The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness...The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed". Thus, a claim may be patentable even if experimentation is required, so long as the experimentation is not undue. In the present case, well-known and straightforward techniques are available for identifying the claimed sequences, allowing the skilled person to perform the claimed methods and obtain the claimed sequences with no undue burden. Therefore, the claimed subject matter is enabled.

Claim 75 step (d) as amended, is based on page 26, lines 7-25 of the description. The method now requires isolation and identification of SEQ ID NO: 1 following positive hybridization. This renders moot the Examiner's objection in

the paragraph bridging pages 11-12 of the office action, that even stringent hybridization conditions do not always select for DNA fragments whose contiguous nucleotide sequence is the same or nearly the same as the probe. Even if the probe were to hybridize with a sequence sharing little overall sequence identity with SEQ ID NO: 1, that hybridization is not per se treated as the sole identification step. Instead, the claim requires the hybridizing nucleic acid to be isolated and identified. Hybridization using a conserved probe is a well-known and frequently used technique in the art, and the claimed methods can be readily carried out by one skilled in the art.

The methods of claims 72-75 and 78 were rejected on the grounds that nucleotide sequences sharing sequence identity do not always encode proteins having the same activity (paragraph bridging pages 12-13 of the office action). The Examiner's analysis of the Bowman et al. and Siegfried et al. papers was that the function of the CRC gene product differs from that of other members of the same ("YABBY") family. However, applicants must point out that these papers actually show that CRC and the related members all show the same function, namely the specification of abaxial cell fate. This is explained for example in Siegfried et al. on page 4127, left hand column, paragraph entitled "The YABBY gene family". Thus, these papers actually serve to demonstrate a link between sequence and function in related sequences.

The methods of claims 72-75 and 78 maximize the chances of identifying the desired sequence through use of a probe whose sequence represents a region that is at least 90 % identical between SEQ ID NO: 1 and related sequences. Because the probe sequence corresponds to a conserved sequence, the chance of hybridization with closely related sequences is higher than if the probe sequence corresponded to a less

conserved part of the sequence.

One skilled in the art is familiar with the techniques required to carry out the claimed methods, and even expects to obtain sequences other than those he is looking for - this is normal. The important fact is that the skilled person can also, without undue burden, obtain the sequences that he is looking for. The Examiner's attention is respectfully drawn to *In re Angstadt and Griffin*, 190 USPQ 214 (CCPA 1976) wherein the Court held that an applicant need not demonstrate the operability of each and every species covered by a claim and that patentable claims may cover inoperable species. In the present situation, the skilled person knows how to perform the claimed methods successfully and to obtain sequences falling within the scope of the claims. Occasional failure to obtain a sequence having the recited properties does not mean that the claimed methods are not enabled. The straightforward nature of the available techniques means that one skilled in the art can successfully perform the claimed methods with no undue experimentation.

Lastly, with regard to the recited function of the claimed sequences, the Examiner notes that transforming plants with heterologous genes that are involved in plant development produces unpredictable results.

The description in the application includes a discussion of techniques that may be used to transform plants with the claimed sequences (e.g. pages 13-17). Transformation of plants can have variable effects, as the Examiner points out. This is true of any biological system - variation is inherent in the nature of the art. When producing transgenic plants, it is normal practice to transform a large number of plants and then to select those displaying the desired effects. Almost certainly, the introduction of functional nucleic acid will not be successful in every plant, and variation is

expected. The experimentation required for successful transformation is normal in the art and is not undue. On the contrary, the variability of the technique is recognized and compensated for by one skilled in the art.

As noted above in reference to *In re Wands*, a need for experimentation does not render the claimed subject matter unpatentable, as long as it is not "undue" experimentation. The introduction of the claimed nucleic acid into a plant to obtain the claimed function requires a level of experimentation that is normal in the art of plant transformation. The functions as claimed are, therefore, reasonable.

In conclusion, the subject matter of the amended claims is fully enabled by the disclosure in the specification. Accordingly, applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

The Claims are Novel Over Schmidt et al.

The Examiner has rejected claims 1-4 and 60-65 under 35 U.S.C. §102(b), as allegedly anticipated by Schmidt et al., *Science* (1995) 270:480-483.

In response, applicants respectfully submit that Schmidt et al., did not place the invention in the hands of the public. See MPEP 2121.01:

"In determining that quantum of prior art disclosure which is necessary to declare an applicant's invention 'not novel' or 'anticipated' within section 102, the stated test is whether a reference contains an 'enabling disclosure'... ." *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968). A reference contains an "enabling disclosure" if the public was in possession of the claimed invention before the date of invention. "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985).

Applicants submit that one of skill in the art could not have combined the teachings of Schmidt et al., with their own knowledge to obtain the instant invention. Schmidt relates to a vast number of YAC clones and their arrangement on chromosome 4. It does not explicitly identify any nucleic acid isolate that regulates physical characteristics of a plant, there being no mention of such function. The claimed invention is directed to explicitly disclosed VRN2 sequences that regulate a physical characteristic of a plant, namely vernalization response, flowering time, leaf size and/or shape or shade avoidance response. It cannot fairly be said that this invention was "described in a printed publication", because the skilled person reading Schmidt would not be made aware of nucleic acid encoding a polypeptide that regulates any such characteristic. Schmidt contains no indication that the YAC clones contain any sequence that regulates a physical characteristic of a plant and, based on Schmidt, one skilled in the art has no reasonable chance of identifying such a sequence. The disclosure is still effectively under lock and key.

The Examiner states that "the VRN2 locus nucleic acid is obtainable from the YAC clones". Practically speaking, the nucleic acid is only obtainable because of the disclosure in the present application. In the prior art, one skilled in the art would not have obtained VRN2 locus nucleic acid from the YAC clone, because the prior art provided no indication that the claimed nucleic acids were obtainable.

Schmidt physically mapped chromosome 4, but did not disclose any nucleotide sequence nor any amino acid sequence. No start codons or stop codons are identified, and no physical, structural, or chemical characteristics are provided. There is therefore, no clear disclosure in Schmidt of a sequence (e.g. SEQ ID NO: 1 and SEQ ID NO: 2) as claimed

in the present application. The Examiner has not shown that the YAC clones contained the exact sequence SEQ ID NO: 1, nor that they encoded SEQ ID NO: 2, nor whether they contained a variant/allele/mutant of SEQ ID NO: 1.

Moreover, various dependent claims are independently novel over Schmidt. For example, claim 62 relates to a VRN2 sequence obtained from a plant other than *Arabidopsis thaliana*. The Schmidt clones are derived from *A. thaliana* only. Therefore, the feature recited in claim 62 is novel.

Another example is claim 64, which relates to a fragment of SEQ ID NO 1. No fragment of SEQ ID NO 1 is disclosed in Schmidt et al.

Accordingly, applicants respectfully assert that the rejection of claims 1-4 and 60-65 under 35 U.S.C. §102(b) is inappropriate and should be withdrawn.


CONCLUSION

In view of the present amendments and foregoing remarks, it is respectfully urged that the rejections set forth in the August 21, 2003 Official Action be withdrawn and that this application be passed to issue.

In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the Examiner is requested to telephone the undersigned attorney at the phone number given below.

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Enclosure-Synopsis of Written Description Guidelines

Annex to responseSYNOPSIS OF APPLICATION OF WRITTEN DESCRIPTION GUIDELINESExample 9: Hybridization**Specification:**

The specification discloses a single cDNA (SEQ ID NO:1) which encodes a protein that binds to a dopamine receptor and stimulates adenylate cyclase activity. The specification includes an example wherein the complement of SEQ ID NO: 1 was used under highly stringent hybridization conditions (6XSSC and 65 degrees Celsius) for the isolation of nucleic acids that encode proteins that bind to dopamine receptor and stimulate adenylate cyclase activity. The hybridizing nucleic acids were not sequenced. They were expressed and several were shown to encode proteins that bind to a dopamine receptor and stimulate adenylate cyclase activity. These sequences may or may not be the same as SEQ ID NO: 1.

Claim:

An isolated nucleic acid that specifically hybridizes under highly stringent conditions to the complement of the sequence set forth in SEQ ID NO: 1, wherein said nucleic acid encodes a protein that binds to a dopamine receptor and stimulates adenylate cyclase activity.

Analysis:

A review of the full content of the specification indicates that the essential feature of the claimed invention is the isolated nucleic acid that hybridizes to SEQ ID NO: 1 under highly stringent conditions and encodes a protein with a specific function. The art indicates that hybridization techniques using a known DNA as a probe under highly stringent conditions were conventional in the art at the time of filing. The claim is drawn to a genus of nucleic acids all of which must hybridize with SEQ ID NO: 1 and must encode a protein with a specific activity. The search of the prior art indicates that SEQ ID NO: 1 is novel and unobvious. There is a single species disclosed (a molecule consisting of SEQ ID NO: 1) that is within the scope of the claimed genus. There is actual reduction to practice of the disclosed species. Now turning to the genus analysis, a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention.

Conclusion:

The claimed invention is adequately described.